

MONTAGE[®]

SETTABLE BONE PUTTY

Contains Hydroxyapatite/ β -TCP and 5% by weight Vitamin E Acetate

MONTAGE SETTABLE BONE PUTTY is a settable (hardening) bioabsorbable polymer and hydroxyapatite/beta tricalcium phosphate-based putty, cleared for use in multiple clinical indications, including bone hemostasis, filling bony voids or gaps in the skeletal system (i.e. extremities and pelvis), and as a cranial bone cement in the repair of neurosurgical burrholes, contiguous craniotomy cuts, and other cranial defects with a surface area no larger than 25cm².

When used as a bone void filler, MONTAGE can be used to augment provisional hardware (e.g. k-wires, plates and screws) and to help support bone fragments during surgical procedures as the hardened putty acts as a temporary support medium. MONTAGE can be drilled and tapped, and hardware can be placed through it at any time during the setting process.

MONTAGE is packaged as two individual putties that, upon being hand-mixed for a minimum of 45 seconds, form a cohesive putty (hand moldable and shapeable) of uniform light tan color and consistency. After mixing, MONTAGE can be immediately applied for bone hemostasis, or to fill bony voids or gaps in the skeletal system (i.e. extremities and pelvis), or as a cranial bone cement for the repair of cranial defects.

A fully-mixed MONTAGE putty can be partitioned into pieces for use in different locations. Any subsequent recombination of the divided putty should be completed shortly after mixing, as MONTAGE begins to harden in minutes following mixing.

Once applied, MONTAGE putty interdigitates, adheres, and expands into the pores of the bone and begins to set (harden), even under normal irrigation conditions.

When used as a bone void filler, MONTAGE may be used to help stabilize a bone / hardware construct intraoperatively and support can be provided to bone fragments prior to the placement of rigid fixation.

When used as a bone void filler, MONTAGE may be shaped, drilled and tapped using standard surgical instruments. Rigid hardware should always be secured within healthy bone.

IMPORTANT APPLICATION INFORMATION

- Before applying MONTAGE, be sure to irrigate and dry to ensure a clean bone surface.
- Using sterile technique and dry gloves, vigorously knead and mix MONTAGE for at least 45 seconds, until MONTAGE is a single, uniform light tan color and consistency.
- Using sterile technique and dry gloves and/or instruments, apply MONTAGE to the bone immediately following mixing. Apply the minimum amount of material sufficient to cover the bone surface or fill the bony gap/void. If the bone surface is not completely covered or the void/gap is not completely filled with the initial application, additional applications of putty may be necessary.
- MONTAGE can be applied with gloved fingers or a blunt surgical instrument with a working end that is larger than the intended area of application.
- The ideal duration of application / working time (for adherence to bone and spreadability) is approximately within two (2) minutes of initiation of mixing.
- Be sure to remove excess MONTAGE.

Under complete submersion in phosphate buffered saline (at 37°C), MONTAGE was found, in a benchtop (in-vitro) study, to have expansion of approximately 9.5%.

MONTAGE does not exceed body temperature (37°C) during the mixing or hardening processes.

The bioabsorbable polymer and hydroxyapatite/beta tricalcium phosphate components are replaced during the bone remodeling process. MONTAGE demonstrated ~30% greater new bone formation in an extremity critical sized defect animal model at the 12-week time point, as compared to a leading settable, calcium phosphate bone void filler.

MONTAGE is MRI safe.

Several pre-clinical studies were completed to assess the biocompatibility, hardening, efficacy, mechanical, and resorption profile of MONTAGE. MONTAGE showed no signs of toxicity or negative tissue reaction. The results of these studies are available upon request by physicians.

MONTAGE is gamma-irradiated and is provided terminally sterilized in packaging that was specifically designed to assure shelf stability.

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KEY CHARACTERISTICS

MONTAGE SETTABLE BONE PUTTY	OTHER SETTABLE CALCIUM PHOSPHATE BONE VOID FILLERS / CEMENTS
COMPONENTS	
Contains absorbable polymer, hydroxyapatite/ beta-tricalcium phosphate, and Vitamin E Acetate	Contains calcium phosphate powder and liquid components
PREPARATION AND HANDLING	
Immediately hand mixable and putty-like in consistency ("Putty-Putty") out of package	Two-part powder and liquid device with manual mixing systems
Immediately cohesive, hand moldable, shapeable, and can be applied following mixing for 45+ seconds or until visually homogeneous	Not cohesive ("paste-like") in consistency and can be applied following mixing in 60+ seconds
APPLICATION	
Interdigitates and expands (~9.5%) in the pores of the bone	Contracts / does not expand
Controls bone bleeding via mechanical tamponade	Must control active bone bleeding prior to application if needed
Develops porosity	Relatively non-porous following hardening
Adheres to bone and resists dislodgement/ remains in place during the hardening process, even under normal irrigation	No adhesive properties; can be washed away during hardening under normal irrigation
When used as a bone void filler, can be drilled and tapped, and hardware can be placed through it any time during the setting process	Not all of these products are indicated to be drilled or tapped



700 Fairfield Avenue, Suite 1 • Stamford, CT 06902 U.S.A. • 1.855.475.9175 • customerservice@abyrx.com • www.abyrx.com

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ABYRX products are made in U.S.A.

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